***United States Court of Appeals***

***for the Second Circuit***


# APPELLANT'S BRIEF

ORIGINAL WITH PROOF OF SERVICE

# 75-6109

## UNITED STATES COURT OF APPEALS

*for the*

## SECOND CIRCUIT

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P/S

ELIZABETH DALEY, M.D.,

Plaintiff- Appellant,

-against-

CASPAR W. WEINBERGER, Secretary of Health, Education and Welfare, ALEXANDER M. SCHMIDT, M.D., Commissioner of the Food and Drug Administration, CLIFFORD G. SHANE, Regional Director of the Food and Drug Administration, TERRY MUSSON, ALLEN R. HALPER, JOHN E. KLEMMER and THOMAS D. GARDINE, Employees of the Food and Drug Administration,

Defendants- Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

BRIEF FOR APPELLANT

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# BRIEF FOR APPELLANT

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## ISSUE PRESENTED

Does a controversy sufficiently ripe for adjudication exist between the parties?

## STATEMENT OF THE CASE

### Preliminary Statement

Following a second attempt by Food and Drug Administration ("FDA") inspectors to enter and inspect her medical office, plaintiff-appellant Elizabeth Daley, M.D., a licensed physician, brought this action under 28 U.S.C. §§ 1331 and 1337 seeking a declaratory judgment that the FDA lacks jurisdiction to investigate, inspect or otherwise enforce the provisions of the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., against a duly-licensed physician engaged in the lawful practice of medicine, and further seeking injunctive relief against such investigation, inspection or enforcement.

Defendants-appellees, the Secretary of Health, Education and Welfare, the Commissioner, Regional Director and four employees of the FDA, moved to dismiss the complaint or in the alternative for summary judgment.

In a memorandum and order dated October 2, 1975, the district court (Neaher, J.) granted defendants' motion for summary judgment and dismissed the complaint on the ground

that a controversy sufficiently ripe for adjudication did not exist between the parties. (A-52).[1/] Plaintiff now appeals from that judgment.

## Statement of Facts

Plaintiff Elizabeth Daley, M.D., is a licensed physician who practices medicine in New York City and maintains an office on the West Side of Manhattan. She suffers from rheumatoid arthritis, and for many years has specialized in the treatment of this disease.

The principal method of treatment employed by plaintiff is based upon three hormones--prednisone, testosterone and estradiol--which are administered to patients in varying combinations and dosages. This form of treatment was originally developed by the late Dr. Robert Liefmann, a Canadian physician, and the various hormonal combinations came to be loosely referred to as "Liefcort."

Prednisone, testosterone and estradiol are well-known, federally-approved drugs. "Liefcort" was essentially a trade name, but does not accurately refer to any specific drug.

On February 10, 1975, defendant Allen R. Halper, an FDA inspector, appeared at plaintiff's Manhattan office for the purpose of conducting an administrative inspection pur-

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1/ "A-" refers to pages of Appellant's Appendix.

suant to Section 704 of the Food, Drug and Cosmetic Act, 21 U.S.C. § 374 (hereafter "Section 704"). Plaintiff was not present at the time, and defendant Halper served an official Notice of Inspection upon plaintiff's nurse. The nurse did not permit the inspection and declined to answer any questions concerning plaintiff's medical practice, except to inform defendant Halper of plaintiff's office hours and refer him to plaintiff's attorneys. (A-25-26).

Thereafter, plaintiff's attorney, Henry B. Rothblatt, had telephone conversations with defendant Halper and other FDA employees concerning the purpose of the FDA investigation. He was informed that the FDA was investigating plaintiff's alleged use of "Liefcort."

On February 24, attorney Rothblatt sent a telegram to defendant John E. Klemmer, of the Regional FDA office, which read as follows:

> WOULD YOU PLEASE INFORM ME THE BASES OF YOUR JURISDICTION TO INTERROGATE A MEDICAL DOCTOR SUCH AS DOCTOR DALEY CONCERNING HER MEDICATION AND PRESCRIPTION AND TREATMENT OF HER PATIENTS AS A DULY LICENSE (sic) PHYSICIAN. AS I TOLD YOU IN OUR TELEPHONE CONVERSATION I WILL BE PLEASED TO DISCUSS ALL ASPECT (sic) OF THESE MEDICATIONS WITH YOUR SUPERIORS AND ATTORNEYS.
>
> HENRY B ROTHBLATT ATTORNEY FOR DR ELIZABETH DALEY.

(A-14).

On February 25, in response to this message, defendant Terry Musson, a Supervisory Consumer Safety Officer of

the FDA, telephoned attorney Rothblatt and advised him that the FDA was investigating plaintiff's alleged use of "Liefcort." In response, Mr. Rothblatt informed defendant Musson that plaintiff was not receiving or distributing "Liefcort," but was prescribing the hormones prednisone, testosterone and estradiol for her patients. He further informed defendant Musson that plaintiff would not permit an inspection of her medical office or submit to interrogation by FDA inspectors, but that she would provide any information the FDA requested concerning medications used in her practice. (A-23).

Two days after this conversation, on February 27, defendants John E. Klemmer and Thomas D. Gardine went to plaintiff's office and served a second Notice of Inspection. Plaintiff's nurse did not permit them to enter or inspect the office. (A-28-29).

The following day, February 28, plaintiff[2/] commenced this action seeking declaratory and injunctive relief against investigation, inspection or other enforcement of the provisions of the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., against her for conduct consisting of "preparing, prescribing and administering approved drugs or combinations thereof to [her] own patients in the course of [her] own medical practice." (A-9).

The amended complaint alleges, inter alia, that the

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2/ Plaintiff was originally joined in this action by an associate, Henry Rosenberg, M.D., but he was subsequently dismissed as a party by stipulation.

drugs prescribed by plaintiff in the course of her medical practice are all fully approved under federal law, and her conduct in preparing, prescribing and administering approved drugs and combinations thereof to her own patients is her lawful right and professional prerogative as a licensed medical practitioner (A-4); that plaintiff offered to fully disclose and openly discuss with FDA officials, through her attorney, all relevant details concerning the medications she prescribes to her patients, but that the FDA declined this offer, and as a result a controversy continues to exist which requires plaintiff to function under a constant threat of impending action against her by the federal government (A-6); that under the alleged circumstances the FDA lacks authority, pursuant to the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., to investigate, inspect or otherwise interfere with plaintiff's medical practice (A-7); that the conduct of the FDA in investigating, inspecting, threatening to do the same, or otherwise interfering with plaintiff's right to practice her profession, is violative of the Fourth, Fifth and Sixth Amendments of the Constitution, the Food, Drug and Cosmetic Act, and the physician-patient privilege (A-7); that the conduct of the FDA is causing plaintiff and her patients irreparable injury in that she is being deprived the Fourth Amendment right to be free from unreasonable search and seizure and the Fifth Amendment right to practice her profession, that continued investigation by the FDA will destroy her professional reputation and prevent her patients from receiving treatment, that she is being

unlawfully subjected to possible criminal prosecution and resulting fine, imprisonment and loss of her license to practice medicine for refusal to permit inspection of her office and/or other violation of the Food, Drug and Cosmetic Act, 21 U.S.C. § 331 (A-6-7).

Plaintiff also moved for a temporary restraining order against further FDA action against her, in support of which she submitted an affidavit which stated, in part:

> For several years my medical practice has concentrated on rheumatoid arthritis and other rheumatic diseases. The method of treatment which I employ is based upon special diet and the administration of various medications. These medications include the hormones prednisone, testosterone and estradiol which are administered in varying dosages according to the particular requirements of the individual patient. This method of treatment has proven to be successful with thousands of patients over a period of many years.
>
> I myself have a serious rheumatoid arthritis condition which is treated with these medications. It is because of this treatment that I am able to continue to function as an active medical practitioner.
>
> * * *
>
> Any medications which are prepared at my office are used soley in the treatment of my own patients as prescribed by me and my colleague, Dr. Henry Rosenberg. Further, any such medications are composed entirely of legally and medically approved drugs.
>
> It is my understanding, and I again have recently been so advised by my attorney, that it is completely lawful for a licensed physician to prepare, prescribe and administer medications in the manner in which I have been so doing.
>
> I cannot overemphasize the efficacy of the method

> of treatment which I employ. It is effective in treating rheumatic disease. To deny this medication and treatment to the thousands of patients that are now using it successfully would result in needless suffering and crippling. This would be an outrageously inhumane act.
>
> My medical practice cannot be conducted under a constant threat of unlawful intrusion by federal inspectors to say nothing of the harm to my professional reputation which results therefrom.
>
> The present situation is intolerable and must be resolved as expeditiously as possible. It is for this reason that I urge the Court to prohibit the Food and Drug Administration from taking any further action in this matter pending final resolution of this controversy.

(A-15-17).

The application for a temporary restraining order and preliminary injunction was thereafter withdrawn upon the government's stipulation that no further action would be taken against plaintiff except upon notice in the pending action.

Defendants then filed a motion to dismiss or in the alternative for summary judgment, essentially claiming that the action is an unconsented suit against the United States barred under the doctrine of sovereign immunity; that the FDA does have statutory authority to investigate and inspect plaintiff's medical office; that no justiciable controversy exists between the parties; and that there is no basis for injunctive relief. (A-18-20).

In support of their motion defendants submitted an affidavit of Paul J. Sage, who, as Assistant to the Director of Regulatory Operations of the Bureau of Drugs of the FDA,

authorized the investigation and inspection of plaintiff (A-38). Also submitted were affidavits of defendant Terry Musson, Supervisory Safety Officer for the FDA, who issued the actual orders to inspect plaintiff's office (A-22); defendant Allen R. Halper, who served the Notice of Inspection on February 7, 1975 (A-25); and defendant John E. Klemmer, who, with defendant Thomas D. Gardine, served the Notice of Inspection of February 27, 1975 (A-28).

Defendants also submitted an affidavit of George J. Gerstenberg, Deputy Regional Director of the New York District of the FDA. The affidavit states that the FDA had received

> . . . a report that Liefcort, a new drug for which no approved New Drug Application is in effect, had been received after shipment in interstate commerce by Dr. Elizabeth Daley and Dr. Henry Rosenberg at their office at 320 West End Avenue, New York, New York, and was being used for the treatment of patients.

(A-30). It further states that the FDA has "reports" demonstrating the "hazardous nature of this drug" and annexes a seven-year-old paper prepared by the Arthritis Foundation concerning the late Dr. Robert Liefmann and "Liefcort." (A-31). The final paragraph of the affidavit reads:

> In the course of my official duties, I initiated a preliminary investigation of the report that Drs. Daley and Rosenberg had received the drug Liefcort and obtained information which led me to believe that the doctors were distributing the drug. Accordingly, I ordered a formal inspection of their premises at 320 West End Avenue, New York, N.Y.

(Id.)

Prior to submitting papers in opposition to defendants' motion for dismissal and summary judgment, plaintiff requested discovery concerning the basis of the FDA's belief that she was receiving or distributing "Liefcort" or any other "hazardous drugs." Defendants moved for a protective order, claiming the requested information was irrelevant, and stating:

> The crucial and only issue before the Court is the authority of officers or employees of the Food and Drug Administration to enter, after the presentation of their credentials and written notice, into the premises of the plaintiffs herein for the purposes of making an inspection pursuant to 21 U.S.C. 374.

(Memorandum of Law in Support of Defendants' Motion For Protective Order, p. 2)

The district court ruled that defendants' motion for a protective order be held in abeyance pending possible resolution of the essentially legal question of the construction of Section 704.

Plaintiff then submitted a memorandum of law in opposition to defendants' motion for dismissal and summary judgment in which she argued that on the basis of the express statutory exemptions in the Food, Drug and Cosmetic Act; its legislative history; official published statements of the FDA Commissioner; judicial interpretation; and writings of experts in the field of food and drug law, the FDA lacks authority to regulate a licensed physician's use of federally-

approved drugs or combinations thereof in the treatment of his own patients. It was further argued that Section 704 expressly exempts licensed physicians from FDA inspection, and also that since the FDA lacks underlying regulatory authority of physicians, defendants' construction of Section 704 is violative of the Fourth Amendment. (Memorandum of Law in Opposition to Defendants' Motion To Dismiss and For Summary Judgment, pp. 7-22).

On July 11, 1975, after hearing oral argument of defendants' motion, the court attempted to resolve the controversy by suggesting that the parties arrange for a voluntary inspection of plaintiff's office, at which counsel would be present. Plaintiff agreed. Defendants, who were represented by government counsel as well as a representative from FDA headquarters in Maryland, refused. (A-45-51).

Thereafter, in a memorandum and order dated October 2, 1975, the district court granted defendants' motion for summary judgment and dismissed the complaint on the ground that the controversy was not sufficiently ripe for adjudication. (A-52).

## SUMMARY OF ARGUMENT ON THE MERITS

While the principal issue on this appeal is whether or not the controversy between the parties is sufficiently ripe for adjudication, we believe a brief examination of plaintiff's basic contentions on the merits is useful in

placing the ripeness question in perspective.

The basis of the FDA's investigation of plaintiff is her alleged use of "Liefcort," an unapproved "new" drug. (A-30-31). The inspections were ordered essentially to determine if this drug was present at plaintiff's medical office. (A-39).

Although not completely accurate, it is helpful to assume, for sake of argument, that "Liefcort" is equivalent to a combination of the three hormones, prednisone, testosterone and estradiol, each of which is federally approved.

Under the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, et seq., (hereafter "the Food and Drug Act"), a licensed physician is permitted to use a federally-approved drug in an unapproved manner, provided such use is limited to his own patients.

> If an approved new drug is shipped in interstate commerce with the approved package insert, and neither the shipper nor the recipient intends that it be used for an unapproved purpose, the requirements of section 505 of the Act are satisfied. Once the new drug is in a local pharmacy after interstate shipment, the physician may, as part of the practice of medicine, lawfully prescribe a different dosage for his patient, or may otherwise vary the conditions of use from those approved in the package insert, without informing or obtaining the approval of the Food and Drug Administration.
>
> This interpretation of the Act is consistent with congressional intent as indicated in the legislative history of the 1938 Act and the drug amendments of 1962. Throughout the debate leading to enactment, there were repeated statements that Congress did not intend the Food and Drug Administration to interfere with medical practice

> and references to the understanding that the bill did not purport to regulate the practice of medicine as between the physician and the patient. Congress recognized a patient's right to seek civil damages in the courts if there should be evidence of malpractice, and declined to provide any legislative restrictions upon the medical profession.

Notice of Proposed Rule Making, submitted by FDA Commissioner Charles C. Edwards, 37 Fed. Reg. 16503 (August 15, 1972).

Similarly, in an article written by an Assistant to the Director for Regulatory Affairs in the FDA Bureau of Drugs and a Professor of Law and Director of the FDA Unit at Temple Law School, the following is stated:

> It should be apparent then that the medical practitioner has considerable freedom and authority for varied use of products.
>
> The physician can use the drugs exactly as labeled, or he may innovate prescriptively as to dosage, duration, concomitant drugs, precautionary recommendations and even new indications. Whether this is done directly or through the pharmacist, the federal law has been devoid of application inasmuch as the physician and pharmacist are engaged in the practice of their professional prerogatives. Therefore, parenteral mixtures as well as other mixtures prepared or prescribed by a physician for use on his own patients in the normal course of his practice are exempt from the new drug requirements and most other federal and state restrictions.

McEniry & Willig, The Federal Food, Drug, and Cosmetic Act and the Medical Practitioner, 29 Food Drug Cosmetic L.J. 548, 552 (November, 1974). Also see FTC v. Simeon Management Corporation, 1975 Trade Cases ¶ 60,223 (N.D.Cal. 1975).

Thus, assuming that "Liefcort" is a "new drug" under the Food and Drug Act, which could not be sold commercially without complying with the new drug procedures (see 21 U.S.C. § 355), this does not mean that plaintiff, a licensed physician, cannot prescribe a combination of the federally-approved component drugs prednisone, testosterone and estradiol to her own patients within the scope of her medical practice. In fact, this is precisely what plaintiff alleges she is doing (A-4, A-16), and there is nothing in the record to the contrary.

The basis of plaintiff's prayer for declaratory and injunctive relief is thus readily apparent. Even if plaintiff prescribes, for her own patients, the combination of drugs which defendants refer to as "Liefcort," this is not in violation of the Food and Drug Act, nor is it activity over which defendants have regulatory jurisdiction.

With specific regard to Section 704, the so-called "factory inspection"[3/] statute upon which defendants rely for authority to inspect plaintiff's office, there is an express exemption as to

> practitioners licensed by law to prescribe or administer drugs and who manufacture, prepare, propogate, compound, or process drugs solely for use in the course of their professional practice.

21 U.S.C. § 374(a)(2). Moreover, since the FDA lacks regulatory

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3/ See generally, Developments in the Law--The Federal Food, Drug, and Cosmetic Act, 67 Harv.L.Rev. 632, 686 (1954); The Drug Amendments of 1962, 38 N.Y.U. L. Rev. 1082, 1110 (1963); Graham, The Law Governing FDA Factory Inspection, 21 Food Drug Cosmetic L.J. 275 (1966); Aarons, Factory Inspection, 22 Food Drug Cosmetic L.J. 407 (1967)

authority over plaintiff's conduct, a warrantless, administrative inspection of her office would be violative of the Fourth Amendment as construed in United States v. Biswell, 406 U.S. 311 (1972) and Colonnade Catering Corp. v. United States, 397 U.S. 72 (1970).4/

## ARGUMENT

### THIS CASE PRESENTS AN ACTUAL CONTROVERSY THAT IS RIPE FOR ADJUDICATION UNDER THE DECLARATORY JUDGMENT ACT.

The controversy existing between plaintiff and defendants is clearly defined. Defendants contend they have the authority, pursuant to Section 704 of the Food and Drug Act (21 U.S.C. § 374), to conduct an administrative inspection of plaintiff's medical office. The record amply demonstrates that defendants fully intend to exercise this purported authority against plaintiff.

It is plaintiff's position that as a state-licensed medical practitioner who prepares and prescribes medications consisting entirely of federally approved component drugs, soley for use of her own patients, she does not fall within the regulatory authority of the FDA. Specifically, she contends that Section 704 does not authorize a warrantless, administrative search of her office.

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4/ The arguments and authorities in support of plaintiff's position are fully set forth in the Memorandum of Law In Opposition to Defendants' Motion To Dismiss And For Summary Judgment, pp. 7-22.

This action was commenced only after the FDA refused to attempt to conduct its investigation of the drug "Liefcort" with plaintiff's cooperation, in some reasonable manner other than inspection of her office. After the action was brought plaintiff eventually agreed to permit the FDA to inspect the office, provided only that the date and time be prearranged so that counsel could be present. This also was refused. It is thus defendants, not plaintiff, who seek confrontation.

It cannot seriously be questioned that under these circumstances an actual controversy, based upon a concrete set of facts, exists between the parties. This is certainly not the case of a litigant seeking an advisory opinion; the judgment requested here will have a very real impact upon the parties--it will either permit or prohibit FDA inspection of plaintiff's office.

In dismissing the complaint the district court held that this controversy was not sufficiently ripe for adjudication. Applying the test of Abbott Laboratories v. Gardner, 387 U.S. 136 (1967), the court wrote:

> While the issue raised appears to be a purely legal one, i.e., the FDA's statutory authority to inspect a physician's office, there is here no final agency action whose legality the court may pass upon. Although FDA agents made two visits to plaintiff's office, no inspection was in fact conducted. The court is reluctant to anticipate what future action, if any, FDA may decide to take.

(A-57).

We contend that the ripeness standard has been misapplied. The district court has misconstrued the concept of "final agency action" and failed to accord sufficient weight to the dilemma facing plaintiff.

Fitness of the Issues for Judicial Resolution

In Abbott Laboratories v. Gardner, supra, after noting that "judicial review of a final agency action by an aggrieved person will not be cut off unless there is a persuasive reason to believe that such was the purpose of Congress," 387 U.S. at 140, the Court set forth the basic guidelines for determining ripeness:

> Without undertaking to survey the intricacies of the ripeness doctrine it is fair to say that its basic rationale is to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties. The problem is best seen in a twofold aspect, requiring us to evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court decision.

387 U.S. at 148-149 (footnote omitted).

Thus the first prong of the test concerns fitness of the issues for judicial resolution. The Court initially noted that the issues were appropriate for judicial decision because "all parties agree that the issue tendered is a purely

legal one: whether the statute was properly construed by the Commissioner . . . ." 387 U.S. at 149. This, of course, is precisely the situation here.[5/] If anything, this case presents an a fortiori situation since only federal statutes rather than administrative regulations are involved, and the question of statutory construction is particularly well suited for judicial examination. See Aquavella v. Richardson, 437 F.2d 397, 404 (2d Cir. 1971).

The next factor emphasized in Abbott was that the agency action under review was final under the "pragmatic" and "flexible" test established in prior cases. 387 U.S. at 149-152. It is this concept which we suggest the court below has misconstrued when it states "there is here no final agency action whose legality the court may pass upon." (A-57).

Agency action takes many forms.[6/] Frequently, the action challenged in a pre-enforcement lawsuit consists of a regulation or order which is claimed to be in excess of statutory authority. See, e.g., Abbott Laboratories v. Gardner, supra, (FDA regulation); Columbia Broadcasting v. United States, 316 U.S. 407 (1942) (FCC regulation); Frozen Food Express v. United States, 351 U.S. 40 (1956) (ICC order). But obviously, other forms of agency action not involving regulations

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5/ Indeed, in opposing plaintiff's request for discovery, defendants argued that "[t]he only issue before the Court is the statutory provisions relating to the administrative inspection." (Memorandum of Law in Support of Motion for Protective Order, p.5).

6/ For example, under the Administrative Procedure Act, 5 U.S.C. 551(13), "agency action" includes "the whole or a part of any agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act."

or published orders are subject to judicial review.

In Aquavella v. Richardson, supra, the Secretary of Health, Education and Welfare suspended Medicare payments to plaintiffs' nursing home. In reversing the district court's dismissal of the complaint, this Court held that the suspension was final agency action. The action was ripe for judicial review because no further administrative action was necessary for resolution of the controversy.

> The resolution of the issue as framed in the complaint would not be aided by any further administrative elaboration of the facts. The complaint challenges the statutory authority of the Secretary to suspend payments and alleges that the procedure denied plaintiffs due process. Without indicating any opinion as to the merits, we note that these issues have traditionally been considered "legal" questions which the courts are particularly well suited to examine. No particular agency expertise is required to resolve whether the Secretary may suspend payments, whether he must give prior notice, or whether he must hold pre- or post-suspension hearings. Although we recognize that agency experience may be relevant to deciding these issues, that experience can be communicated to the court as part of the record, in argument or in a brief.

437 F.2d at 404.7/

In the present case, the agency action consists of the FDA's interpretation of Section 704 of the Food and Drug

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7/ Also see National Automatic Laundry and Cleaning Council v. Schultz, 443 F.2d 689 (D.C. Cir. 1971) (Letter of Wage-Hour Administrator interpreting provision of the Fair Labor Standards Act held to be final agency action and reviewable); Independent Broker-Dealers' Trade Association v. Securities & Exchange Comm., 442 F.2d 132 (D.C. Cir. 1971) (Letters of SEC Commissioner to New York Stock Exchange which led to stock exchange abondonment of customer directed "give-ups" held to be reviewable agency action).

Act, and its attempt, on two separate occasions, to enter and inspect plaintiff's office pursuant thereto.7/ Under the "pragmatic" and "flexible" test of Abbott Laboratories v. Gardner, supra, this was final agency action.

The initial order to inspect plaintiff's office was hardly a low level administrative decision. The investigation and inspection were ordered by Paul J. Sage, Assistant to the Director of the Division of Regulatory Operation of the FDA Bureau of Drugs. (A-39).

After plaintiff's refusal to permit this inspection, a period of negotiations ensued, during which her attorney challenged the FDA's authority, but also expressed her willingness to cooperate in some manner other than inspection. The FDA's response was to serve a second Notice of Inspection. Certainly we may properly assume that the decision to pursue that course, rather than accept plaintiff's offer of cooperation, was a considered judgment of the agency.

Furthermore, throughout this litigation, the FDA has steadfastly maintained its interpretation of Section 704. At oral argument of defendants' motion for dismissal and summary judgment plaintiff agreed to permit FDA inspectors to enter her office and examination her medications, provided only that the date and time be prearranged so that counsel could be present. The FDA, which was represented by government counsel as well as

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7/ This is the only FDA action directed against plaintiff of which she is presently aware. It is quite possible, if not probable, that other action has been taken in the "Liefcort" investigation of which she is unaware.

its own representative from Maryland headquarters, refused. (A-45-51).

In view of this record, the construction of Section 704 presently urged by defendants is certainly a "considered and formalized determination" of the FDA. Toilet Goods Association v. Gardner, 387 U.S. 158, 162 (1967). As such, it is judicially reviewable, final agency action.

Hardship to the Parties of Withholding Court Consideration

The second prong of the Abbott test concerns hardship to the parties of withholding judicial relief.

Prior to the commencement of this lawsuit, plaintiff had twice refused to permit FDA inspection of her office pursuant to 21 U.S.C. § 374. 21 U.S.C. § 331, which is entitled "Prohibited acts," provides in pertinent part:

> The following acts and the causing thereof are prohibited:
>
> * * *
>
> (f) The refusal to permit entry or inspection as authorized by section 374 of this title.

21 U.S.C. § 333 further provides:

> (a) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.

Thus plaintiff faces criminal prosecution and possible fine and/or imprisonment for refusing these inspections. While it is not possible to determine whether the government

will actually bring such an enforcement proceeding against plaintiff, the mere possibility is sufficient to warrant pre-enforcement review.

In Gardner v. Toilet Goods Association, 387 U.S. 167, 172 (1967), where cosmetics manufacturers were permitted pre-enforcement review of regulations which imposed possible criminal sanctions, the Court wrote:

> Faced with these regulations the respondents are placed in a quandary. On the one hand they can, as the Government suggests, refuse to comply, continue to distribute products that they believe do not fall within the purview of the Act, and test the regulations be defending against government criminal, seizure, or injunctive suits against them. We agree with respondents that this proposed avenue of review is beset with penalties and other impediments rendering it inadequate a satisfactory alternative to the present declaratory judgment action.

Similarly, in Doe v. Bolton, 410 U.S. 179, 188 (1973), the Court permitted the physician-appellants to obtain declaratory relief against the Georgia abortion statutes though none of them had even been threatened with prosecution:

> [T]he physician-appellants, who are Georgia-licensed doctors consulted by pregnant women, also present a justiciable controversy and do have standing despite the fact that the record does not disclose that any one of them has been prosecuted, or threatened with prosecution, for violation of the State's abortion statutes. The physician is the one against whom these criminal statutes directly operate in the event he procures an abortion that does not

> meet the statutory exceptions and conditions. The physician-appellants, therefore, assert a sufficiently direct threat of personal detriment. They should not be required to await and undergo a criminal prosecution as the sole means of seeking relief. . . .

The reasoning of both cases applies here a fortiori. For in the present case, plaintiff faces prosecution for acts already committed.

The administrative summons cases cited by the district court presented circumstances quite different from those here. In Reisman v. Caplin, 375 U.S. 440 (1964), the Court held that declaratory and injunctive relief was improper in view of the available administrative procedure, which guranteed the summoned party a full judicial hearing at which the validity of the summons could be challenged. The party could suffer sanctions only if he refused to comply with an order of the judge at such a hearing. Criminal prosecution for a good-faith challenge to the summons was expressly prohibited. Anheuser-Busch Inc. v. Federal Trade Commission, 359 F.2d 487 (8th Cir. 1966), relies heavily upon and is virtually identical to Reisman, supra, for present purposes.

In the present case, the instant proceeding is the only means for plaintiff to test her interpretation of the statute in question without risking criminal sanctions.[8/]

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8/ It should be noted that 21 U.S.C. § 335, which provides an opportunity for a hearing prior to commencement of criminal enforcement proceedings, has been held not to be a prerequisite for prosecution. United States v. Dotterweich, 320 U.S. 277 (1943).

Even if the FDA chose to proceed civilly against plaintiff under 21 U.S.C. §332 to compel compliance with Section 704, such a proceeding would be most injurious to her reputation in the sensitive medical profession. (Compare Abbott Laboratories v. Gardner, supra, 387 U.S. at 153, where the Court emphasized the sensitivity of the drug industry).

Moreover, the hardship to plaintiff of withholding judicial review is not limited to the consequences of possible enforcement proceedings. As plaintiff emphasized in her affidavit submitted in support of injunctive relief:

> My medical practice cannot be conducted under a constant threat of unlawful intrusion by federal inspectors to say nothing of the harm to my professional reputation which results therefrom.
>
> The present situation is intolerable . . . .

(A-17).

What possible justification can be found for permitting a situation to continue whereby plaintiff is left in a permanent state of uncertainty, not knowing when FDA inspectors will next appear at her office door, or when the agency will seek civil or criminal sanctions against her. With no alternative remedy available to her, she will be left helplessly and indefinitely at the mercy of the FDA. Is this not precisely what declaratory judgment was intended to avoid?

## CONCLUSION

For the foregoing reasons, the judgment of the district court should be reversed, and the case remanded for consideration of the merits.

Respectfully submitted,

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STATE OF NEW YORK )
COUNTY OF NEW YORK) ss.:

EDMUND R. MARINELLI, being duly sworn, deposes and says that deponent is not a party to the action, is over 18 years of age and resides at 1135 UNIVERSITY AVE. BRONX, N.Y.

That on the 17th day of FEBRUARY, 1976, deponent personally served the within BRIEF FOR APPELLANT upon the attorneys designated below who represent the indicated parties in this action and at the addresses below stated which are those that have been designated by said attorneys for that purpose.

By leaving 2 true copies of same with a duly authorized person at their designated office.

~~By depositing true copies of same enclosed in a postpaid properly addressed wrapper, in the post office or official depository under the exclusive care and custody of the United Stated post office department within the State of New York.~~

Names af attorneys served, together with the names of the clients represented and the attorneys' designated addresses.

DAVID G. TRAGER ESQ.
UNITED STATES ATTORNEY FOR THE EASTERN DISTRICT
OF NEW YORK. ATTORNEY FOR DEFENDANTS-APPELLEES
BY CYRIL HYMAN, ESQ. ASSISTANT U.S. ATTORNEY
225 CADMAN PLAZA EAST
BROOKLYN. N-Y. 11201

Edmund R. Marinelli

Sworn to before me this
17th day of February, 1976
Michael DeSantis

MICHAEL DeSANTIS
Notary Public, State of New York
No. 03-0930908
Qualified in Bronx County
Commission Expires March 30, 1977